DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 2, 2014

Endoshape, Inc.
Michael Parmenter
Director, Regulatory Affairs and Quality Assurance
2450 Central Ave, Suite I
Boulder, Colorado 80301

Re: K140796
Trade/Device Name: Medusa Vascular Plug
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 16, 2014
Received: October 17, 2014

Dear Michael Parmenter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kenneth J. Cavanaugh -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140796

Device Name
Medusa™ Vascular Plug

Indications for Use *(Describe)*
The Medusa™ Vascular Plug is intended for arterial and venous embolizations in the peripheral vasculature. The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and guide wires should be employed.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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APPENDIX A

510(K) SUMMARY

510(k) Notification K140796

GENERAL INFORMATION

Applicant:

EndoShape, Inc.

Phone: 303-951-6898

Contact Person:

Michael Parmenter
Quality Manager
EndoShape, Inc.
Phone: 303-951-6898 x106
Fax: 303-416-8849

Date Prepared:

March 31, 2014

DEVICE INFORMATION

Trade Name:

Medusa™ Vascular Plug

Generic/Common Name:

Vascular Embolization Device

Classification:

21 CFR§870.3300, Class II

Product Code:

KRD

PREDICATE DEVICE

- Medusa™ Vascular Plug (K123696)

INDICATIONS FOR USE

The Medusa™ Vascular Plug is intended for arterial and venous embolizations in the peripheral vasculature. The product is intended for use by physicians trained and experienced in embolization techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and guide wires should be employed.

DEVICE DESCRIPTION

The Medusa™ Vascular Plug is a coil-based occlusion device intended for embolization procedures in the peripheral vasculature. The Medusa™ Vascular Plug consists of an implant and a delivery system. The implant is constructed of multiple polymer coils that are pre-loaded on to the delivery system. The Medusa™ Vascular Plug coils are delivered concurrently for vascular occlusion in a single application. Like predicate embolic coils, vascular occlusion with the Medusa™ Vascular Plug is achieved by mechanical flow restriction resulting from coil pack delivery that leads to thrombus formation and rapid cessation of blood flow.

SUBSTANTIAL EQUIVALENCE

The Medusa™ Vascular Plug (Epsilon models MVP-020, MVP-022, and MVP-025) and the predicate device, the Medusa™ Vascular Plug (Delta model MVP-020), have the same intended use and use similar technological characteristics to achieve the same mechanism of action. The minor changes implemented to create the Epsilon MVP-020 include:

- Revised control handle design to improve ergonomics, simplify detachment process, and incorporate graphical instructions
- Shortened implant by 2.5% to accommodate new control handle design
- Removed positioning marker bands from coils – initial positioning is now controlled by revised control handle
- Updated IFU to reflect modified handle design and delivery instructions
- Modified subassemblies to improve manufacturability, including:
    - Distal and proximal PEEK end pieces modified from a two-piece assembly to a single part to eliminate an adhesive joint
    - Proximal wire modified from ball wire to loop wire to replace an interference fit and single adhesive joint with two redundant adhesive joints
    - Reshaped proximal PEEK end piece to accommodate wire loop interlock design
- Modified positioning of thrombogenic fibers from placement on 5 of 7 coils to placement on all 7 coils while maintaining the same number and amount of thrombogenic fibers.

All technological characteristics that are unique to the Epsilon Medusa™ Vascular Plug have been validated to raise no new issues of safety or effectiveness. Therefore, the Epsilon Medusa™ Vascular Plug is substantially equivalent to the Delta Medusa™ Vascular Plug.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

All necessary performance testing was conducted on the Epsilon Medusa™ Vascular Plug to support a determination of substantial equivalence to the predicate device. The non-clinical, bench, and animal testing included:

- Design verification studies
- *In-vivo* animal validation study
- Sterilization
- Packaging and shelf-life

The collective results of the non-clinical testing demonstrate that the Medusa™ Vascular Plug meets the established specifications necessary for consistent performance for its intended use.

ANIMAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

In-vivo animal testing was conducted to demonstrate that the Epsilon Medusa™ Vascular Plug models exhibit substantially equivalent performance to the Delta Medusa™ Vascular Plug model MVP-020 with regard to parameters that cannot be confirmed in bench testing. Stability, size of coil pack, and occlusion time for the Epsilon Medusa™ Vascular Plug were measured in an ovine model to provide a direct comparison to performance of the Delta Medusa™ Vascular Plug.

The Epsilon Medusa™ Vascular Plug exhibited performance equivalent to the predicate Delta Medusa™ Vascular Plug, resulting in comparable stability, comparable coil pack lengths, and comparable occlusion times. At the same time, the Epsilon Medusa™ Vascular Plug did not exhibit any acute complications, or raise any other questions of safety, demonstrating that it is as safe as the predicate Delta Medusa™ Vascular Plug. The Epsilon Medusa™ Vascular Plug was shown to be substantially equivalent to the predicate Delta Medusa™ Vascular Plug in this acute study and the results support a substantially equivalent determination.

CONCLUSION

The results of the nonclinical testing demonstrate that the new technological characteristics employed by the Medusa™ Vascular Plug do not raise any new issues of safety or effectiveness. Therefore, the Medusa™ Vascular Plug is substantially equivalent to the predicate devices.